

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY  
SHMUEL SHOHAM, M.D. on 01/19/2017

DEPOSITION OF

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MASSACHUSETTS

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:  
IN RE: NEW ENGLAND :  
COMPOUNDING PHARMACY, INC. :  
PRODUCTS LIABILITY LITIGATION: MDL NO. 2419  
:  
This Documents Relates to: : Master Docket  
: 1:13-MD-02419-RWZ  
All Cases against the Box :  
Hill Defendants :  
:  
-----X

DEPOSITION OF  
SHMUEL SHOHAM, M.D.

THURSDAY, JANUARY 19, 2017  
10:00 a.m.

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Before: Linda Bahur, RPR



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Pages 2..5

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1A P P E A R A N C E S

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1I N D E X

2Videotaped Deposition of:

3SHMUEL SHOHAM, M.D.

4Examination by Mr. Kirby

5

6

7E X H I B I T S

8(Attached to the transcript)

9No.

10Exhibit 1612-1 Notice of Deposition

11Exhibit 1612-2 Report of Dr. Shoham

12Exhibit 1612-3 Curriculum vitae, 8/25/16

13Exhibit 1612-4 Trial and Deposition List,

142011-Present

15Exhibit 1612-5 Letter dated 10/20/16 re

16invoice

17Exhibit 1612-6 Maryland Board of Pharmacy News

18Newsletter, Fall 2012

19

20C I T E D

21Exhibit 1585-12 New England Compounding Center

22Customer List since May 21, 2012,

23Sorted by State

24Exhibit 1089 Article, "Spinal and Paraspinal

25Fungal Infections Associated

with Contaminated

Methylprednisolone Injections"

Exhibit 1619-10 Article, "Price of Cost Savings"

24

25

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1P R O C E E D I N G S

2Whereupon,

3SHMUEL SHOHAM, M.D.

4having been first duly sworn, was examined and

5testified as follows:

6EXAMINATION BY MR. KIRBY:

7Q Morning, Dr. Shoham.

8A Morning.

9Q I introduced myself before off the

10record. But for the record, I'm Greg Kirby, and this

11is Catherine Steiner, and we represent Dr. Bhambhani,

12Dr. Bhambhani's LLC, and Box Hill Surgery Center, LLC.

13Can you spell your name for the record,

14state and spell your name for the record?

15A The name is Shmuel Shoham. And it's

16spelled S-H-M-U-E-L, last name S-H-O-H-A-M.

17Q And if I mispronounce it at all, just

18correct me, okay? I will do my best.

19What's your address, your business address?

20A 1830 East Monument Street, Baltimore,

21Maryland.

22Q Okay. You're under oath. You know that,

23right? This is my only opportunity to find what your

24opinions are, so I'm hopeful to get complete answers.

25To that end, if I ask a question that you don't

Page 5

1understand, can you just ask me to repeat it or

2rephrase it?

3A Yes.

4Q And if you answer a question, I'll assume

5that you understood the question, that you answered it

6as completely as you could. Is that fair?

7A Yes.

8Q Okay. The court reporter is typing down

9everything that we say, and so she can't record nods

10of the head or uh-hums, uh-uhs, that kind of stuff.

11So we just need to make sure we say yes or no.

12It's normal in conversation that we might

13end up talking over each other. I'll do my best not

14to do that, if you can do that as well.

15A Yes.

16Q And if you need a break at any point, just

17let me know and we can take a break. Okay?

18A Yes.

19Q The plaintiffs' counsel identified you as

20an expert on behalf of the plaintiffs. Is that your

21understanding as to why you are here?

22A Yes.

23(Exhibit No. 1612-1 was marked for

24identification.)

25Q I want to mark -- I'll show you what's been



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<p style="text-align: right;">Page 42</p> <p>1 going to give opinions about -- you were going to give</p> <p>2 opinions concerning being a medical doctor, in</p> <p>3 general, not a pain specialist?</p> <p>4 MS. KASPUTYS: Objection.</p> <p>5 A That's what we talked about. But they</p> <p>6 weren't telling me what to do. They were saying that</p> <p>7 that is something that I can do.</p> <p>8 Q They said it's something you can do?</p> <p>9 A As I recall. I don't recall the specific</p> <p>10 words.</p> <p>11 Q And did that have to do with standard of</p> <p>12 care or what did it have to do with?</p> <p>13 A Standard of care.</p> <p>14 Q So why don't you give me your opinions with</p> <p>15 regards to that, as a medical doctor, and how it</p> <p>16 relates to a standard of care in this case.</p> <p>17 A So my opinions regarding standard of care</p> <p>18 in this case are in the report.</p> <p>19 Q Okay. But can you point me to where it is?</p> <p>20 A Page 3 is a specific example.</p> <p>21 Q What part of page 3?</p> <p>22 A Third paragraph.</p> <p>23 Q Okay. So let's look at the first</p> <p>24 paragraph, the first full paragraph on page 3. It</p> <p>25 says, "The manner by which the contaminated steroids</p>	<p style="text-align: right;">Page 44</p> <p>1 applicable to prescribing prescription medicines," and</p> <p>2 then describes, I guess, some other opinions in here.</p> <p>3 But what Maryland law are you referring to?</p> <p>4 A I can give you -- the specific newsletter</p> <p>5 is number 13 on page 5, Board of Pharmacy Newsletter,</p> <p>6 Fall 2012.</p> <p>7 Q Okay. Do you have a copy of that?</p> <p>8 MS. KASPUTYS: That's in the documents that</p> <p>9 were produced for you. Third tab.</p> <p>10 MR. COREN: Third tab?</p> <p>11 MR. KIRBY: I'm not saying you didn't send</p> <p>12 it out. I'm just saying I don't see a copy of it.</p> <p>13 MS. KASPUTYS: Greg, I'll give you one to</p> <p>14 look at.</p> <p>15 MR. KIRBY: Okay.</p> <p>16 MS. KASPUTYS: If I can get it out of the</p> <p>17 binder. There you go.</p> <p>18 MR. KIRBY: Thanks.</p> <p>19 MS. KASPUTYS: Oh, wait a minute. Let me</p> <p>20 give you the rest of the pages. There you go.</p> <p>21 MR. KIRBY: I'd like to mark this as an</p> <p>22 exhibit. Can we make a copy?</p> <p>23 MS. KASPUTYS: Go ahead. You can use that.</p> <p>24 Just take it. I have a stapler if you need one.</p> <p>25 BY MR. KIRBY:</p>
<p style="text-align: right;">Page 43</p> <p>1 reached patients did not always conform to the</p> <p>2 standards of care. A specific example is the method</p> <p>3 and manner in which PF MPA from NECC was prescribed,</p> <p>4 ordered, and administered at Box Hill Surgery Center</p> <p>5 in Maryland."</p> <p>6 So what do you mean by that? Like, be more</p> <p>7 specific.</p> <p>8 A So the way that the products were</p> <p>9 prescribed, according to the testimony that I've read,</p> <p>10 were that patients who had previously been seen at the</p> <p>11 surgical center, their names were provided as a list</p> <p>12 and vials were ordered using those names.</p> <p>13 And then those vials would come and those</p> <p>14 vials were sometimes given to patients who were</p> <p>15 different than the ones that it was prescribed for.</p> <p>16 And additionally, the single use vials were at times</p> <p>17 used more than one time for one patient for one</p> <p>18 procedure.</p> <p>19 Q Okay. You've never purchased drugs for an</p> <p>20 ambulatory surgery center before, right?</p> <p>21 A Not that I recall.</p> <p>22 Q Okay. And you don't generate, manage, and</p> <p>23 treat chronic pain patients, correct?</p> <p>24 A That is correct.</p> <p>25 Q Now, it says in here "under Maryland law</p>	<p style="text-align: right;">Page 45</p> <p>1 Q Doctor, have you found the newsletter you</p> <p>2 were referring to in your binders?</p> <p>3 A Yes. It's on page 7 of the newsletter</p> <p>4 that's called "Maryland Board of Pharmacy News," Fall</p> <p>5 2012.</p> <p>6 Q I'm sorry, can you say that one more time?</p> <p>7 A Maryland Board of Pharmacy News, Fall 2012,</p> <p>8 page 7.</p> <p>9 Q Okay. So we're going to mark this, it's</p> <p>10 the same thing you have, as 1612-6, for the record.</p> <p>11 (Exhibit No. 1612-6 was marked for</p> <p>12 identification.)</p> <p>13 Q As a physician, you don't regularly receive</p> <p>14 newsletters from the Board of Pharmacy, do you?</p> <p>15 A I may. I'm not sure.</p> <p>16 Q Okay. You don't seek out and review</p> <p>17 newsletters from the Board of Pharmacy, do you?</p> <p>18 A In preparation for this case, I reviewed</p> <p>19 this material.</p> <p>20 Q So I mean, in the normal course of your</p> <p>21 practice.</p> <p>22 A I may receive it.</p> <p>23 Q You're talking about you receive Maryland</p> <p>24 Board of Pharmacy newsletters?</p> <p>25 A I may. I'm not sure.</p>

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<p style="text-align: right;">Page 54</p> <p>1 said, so...</p> <p>2 BY MR. KIRBY:</p> <p>3 Q What is it specifically about these</p> <p>4 prescriptions? What did Dr. Bhambhani need to put on</p> <p>5 each prescription -- on each prescription that would</p> <p>6 have been different for patient A versus patient D?</p> <p>7 A I think it depends on the patient. I can</p> <p>8 speak to an individual patient with an individual</p> <p>9 prescription.</p> <p>10 Q Is it your understanding that Dr. Bhambhani</p> <p>11 was using the MPA at issue kind of in an office supply</p> <p>12 situation?</p> <p>13 A Yes.</p> <p>14 Q And is it your understanding that it didn't</p> <p>15 matter to her whether she used vial 1 or vial 12, it</p> <p>16 was going to be the same for each patient?</p> <p>17 MR. COREN: Objection to form.</p> <p>18 A I don't know that.</p> <p>19 Q Okay. You don't know one way or the other?</p> <p>20 A I don't know that.</p> <p>21 Q Is there anything else that you have with</p> <p>22 regards to your opinion about how Dr. Bhambhani</p> <p>23 breached the standard of care in ordering the drugs?</p> <p>24 MS. KASPUTYS: Objection to form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 56</p> <p>1 Q Okay. So you're not sure what</p> <p>2 relationship -- what type of relationship they had?</p> <p>3 A I'm not sure.</p> <p>4 Q Would you agree that Dr. Bhambhani was</p> <p>5 ordering the MPA for general use in her ambulatory</p> <p>6 surgery center?</p> <p>7 MR. COREN: Objection as to form.</p> <p>8 A It seems that way, but I'm not sure of that</p> <p>9 because she was using specific patient names.</p> <p>10 Q Typically when we think of prescriptions,</p> <p>11 we think of a patient getting a piece of paper and</p> <p>12 taking it to CVS or the doctor sending us, you know, a</p> <p>13 piece of paper to the pharmacy for the drug so that</p> <p>14 the patient can pick it up and take it home, right?</p> <p>15 A No.</p> <p>16 Q Okay. Well, tell me what -- I mean, isn't</p> <p>17 that generally what people think of when they think</p> <p>18 about getting a prescription drug?</p> <p>19 MR. COREN: Objection as to form.</p> <p>20 A I don't know what people think of.</p> <p>21 Q Okay. Regardless, that's not what we're</p> <p>22 dealing with here, right? I mean, the patients in</p> <p>23 these cases never handled the MPA, right?</p> <p>24 A I don't know.</p> <p>25 Q Is it your understanding that</p>
<p style="text-align: right;">Page 55</p> <p>1 A Can you repeat your question?</p> <p>2 Q I'm just trying to exhaust your opinions.</p> <p>3 Is there anything else that we haven't talked about</p> <p>4 with regards to how Dr. Bhambhani ordered the drugs at</p> <p>5 issue that you say was wrong?</p> <p>6 A If we can go to her deposition, or one of</p> <p>7 the depositions mentioned getting medications from</p> <p>8 another clinic, I believe.</p> <p>9 Q Okay. Feel free to look at her deposition.</p> <p>10 So feel free to keep looking if you want.</p> <p>11 But can you recall anything off the top of your head</p> <p>12 about what you were referring to?</p> <p>13 A What I recall off the top of my head was</p> <p>14 that there were medications that were obtained by the</p> <p>15 Box Hill center from another surgical center.</p> <p>16 Q Okay. And tell me what you believe was the</p> <p>17 problem with that. What's your criticism?</p> <p>18 A That if a medication for a specific person</p> <p>19 that's prescribed should be coming from the</p> <p>20 manufacturer or from a pharmacy, not from another</p> <p>21 center.</p> <p>22 Q Do you have an understanding of what</p> <p>23 Dr. Bhambhani's relationship was with that other</p> <p>24 ambulatory surgery center you just referred to?</p> <p>25 A Not a good understanding.</p>	<p style="text-align: right;">Page 57</p> <p>1 Dr. Bhambhani -- well, tell me how you think she was</p> <p>2 ordering the drug from NECC.</p> <p>3 A Well, what I think that she was doing was</p> <p>4 sending in lists of patients for whom the drug may or</p> <p>5 may not be given and ordering the drug for those</p> <p>6 patients and then using it either for those patients</p> <p>7 or for other patients.</p> <p>8 Q And what's your basis for saying that?</p> <p>9 A The deposition of Dr. Bhambhani and of</p> <p>10 Nurse Vickers and the exhibits of the deposition.</p> <p>11 Q Okay. So it's your understanding that she</p> <p>12 was ordering drugs -- is it your understanding that</p> <p>13 she was ordering drugs per the instructions of NECC?</p> <p>14 MR. COREN: Objection as to form. You can</p> <p>15 answer.</p> <p>16 A I believe that it was a combination of the</p> <p>17 instructions from NECC and the advice that she had</p> <p>18 received from the nurse she was working with then from</p> <p>19 the other center that she had worked with.</p> <p>20 Q Okay. And she was ordering, using</p> <p>21 something that said -- a one sheet of paper that said</p> <p>22 "Prescription Order Form" at the top. Are you aware</p> <p>23 of that?</p> <p>24 A Yes.</p> <p>25 Q Okay. And you're saying she was listing</p>

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<p style="text-align: right;">Page 102</p> <p>1 spine -- okay. So let me step back.</p> <p>2 A lot of these patients may have already</p> <p>3 had irritation or inflammation around the nerves of</p> <p>4 the spine. That's what brought them to a healthcare</p> <p>5 provider to get injections. Fair enough?</p> <p>6 MR. COREN: Objection to form.</p> <p>7 A I don't agree.</p> <p>8 Q Okay. What don't you agree with?</p> <p>9 A I don't know the specifics of what brought</p> <p>10 patients to the spinal -- to the pain specialist? Is</p> <p>11 that --</p> <p>12 Q Correct.</p> <p>13 A Irritation could be one cause, but there</p> <p>14 could be many reasons why patients end up seeing a</p> <p>15 pain specialist.</p> <p>16 Q Okay. In an average everyday person who is</p> <p>17 not suffering from back pain, is there some</p> <p>18 anticipated number of white cells that they may have</p> <p>19 in their cerebrospinal fluid if you were to test them?</p> <p>20 A Less than 5 cells per cubic milliliter.</p> <p>21 Q So that could just be the average person</p> <p>22 that's not suffering any back problems?</p> <p>23 A That is a normal -- the expectation from a</p> <p>24 noninflamed, noninfected person.</p> <p>25 Q You wouldn't be concerned or -- you</p>	<p style="text-align: right;">Page 104</p> <p>1 CSF as result of nonmeningitis inflammation around the</p> <p>2 spine?</p> <p>3 A If the spinal fluid and the meninges are</p> <p>4 inflamed, that is meningitis. The definition of</p> <p>5 meningitis is inflammation of the meninges.</p> <p>6 Q Okay.</p> <p>7 A For whatever cause.</p> <p>8 Q Would an epidural injection itself lead to</p> <p>9 a recruitment of white blood cells to the area?</p> <p>10 A Potentially.</p> <p>11 Q When you say potentially, is there a</p> <p>12 percentage of patients that you would expect that?</p> <p>13 A I don't know.</p> <p>14 Q Might you have a recruitment of white cells</p> <p>15 that's greater than 5 after just a regular epidural</p> <p>16 injection with no sequelae?</p> <p>17 A It's possible.</p> <p>18 Q Okay. As we all sit here today, we're</p> <p>19 breathing in mold spores, right?</p> <p>20 A Potentially.</p> <p>21 Q I mean, they're generally all around us?</p> <p>22 A Potentially.</p> <p>23 Q Almost done. Famous last words.</p> <p>24 Can we agree that the contamination of the</p> <p>25 MPA with exserohilum rostratum, or fungus, was caused</p>
<p style="text-align: right;">Page 103</p> <p>1 wouldn't concerned if you got that lab result, right?</p> <p>2 Less than 5 white blood cells?</p> <p>3 A I would not be concerned by that particular</p> <p>4 number in general. There are patients where I would</p> <p>5 be very concerned.</p> <p>6 Q Let's assume that a patient does have</p> <p>7 inflammation around the spine, or irritation. They</p> <p>8 don't have -- let's assume they don't have meningitis,</p> <p>9 okay? They're just a patient who has inflammation</p> <p>10 around the spine and they get a tap. They get a</p> <p>11 lumbar puncture. Is there an anticipated level of</p> <p>12 white blood cells that person could have in their CSF?</p> <p>13 A So this is a patient that does not have</p> <p>14 meningitis?</p> <p>15 Q Correct.</p> <p>16 A Less than 5 cells.</p> <p>17 Q Okay.</p> <p>18 A Part of the definition of meningitis is</p> <p>19 more than 5 cells.</p> <p>20 Q I guess what I'm trying to find out is does</p> <p>21 the fact that somebody who doesn't have meningitis,</p> <p>22 already has inflammation in the nerves around the</p> <p>23 spine, and you could have a response from white blood</p> <p>24 cells to inflammation, right? Would you expect that</p> <p>25 there might already be some white blood cells in the</p>	<p style="text-align: right;">Page 105</p> <p>1 by NECC? If you don't know, then that's fine, too.</p> <p>2 A Ask the question again.</p> <p>3 Q Can we agree that the fact that the MPA was</p> <p>4 contaminated with E. rostratum or some other microbe,</p> <p>5 that that was caused by NECC?</p> <p>6 MS. KASPUTYS: Objection to form.</p> <p>7 Q So let me start that over just for</p> <p>8 foundation.</p> <p>9 If we know that E. rostratum was the cause</p> <p>10 of many or most, I guess, of the infections in this</p> <p>11 case, right?</p> <p>12 A We know that it caused some of the</p> <p>13 infections.</p> <p>14 Q So can we agree that NECC caused the</p> <p>15 contamination?</p> <p>16 A We know that the contamination was present</p> <p>17 in the vials that were unopened that were present at</p> <p>18 NECC.</p> <p>19 Q Okay. That's a good answer.</p> <p>20 You mentioned earlier, and I had skipped</p> <p>21 over it, but regards to your opinions, you said that</p> <p>22 you thought that Dr. Bhamhani breached standards of</p> <p>23 practice by the use of the vial multiple times, I</p> <p>24 think. Do you recall that?</p> <p>25 A So use of a single-use vial multiple times</p>



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<p style="text-align: right;">Page 106</p> <p>1 for multiple patients or for multiple procedures in 2 the same patient is not standard of care. 3 Q Okay. And are you familiar with any 4 literature that suggests that, I guess, "single-dose 5 dose vials can be used on multiple patients under 6 certain circumstances with certain precautions that 7 are taken"? 8 A I have seen a reference that is an opinion 9 by some people. 10 Q Okay. So you wouldn't disagree that some 11 in medicine accept the practice of using single-dose 12 vials multiple times as long as they follow certain 13 precautions? 14 A That is an opinion. That is not what the 15 CDC recommends. The CDC recommends against it. 16 Q All right. If other reasonably prudent 17 practitioners believe that it's okay to do it as long 18 as there are certain precautions taken, isn't that the 19 definition of standard practice? 20 MR. COREN: Objection as to form. 21 MS. KASPUTYS: Object to form. 22 Q Maybe not everyone agrees. You have one. 23 Someone else has a different opinion. But that 24 doesn't mean that just because it's different than 25 your opinion that it's wrong, correct?</p>	<p style="text-align: right;">Page 108</p> <p>1 A Yes. 2 Q "And the push for cost-efficient care, a 3 case can made for safely reusing a single-dose 4 medication." See that? 5 A I see that. 6 Q And then under there, it's a description of 7 -- I'm just going to read it. You can follow along. 8 It says, "If a practitioner chooses to reuse a 9 single-dose medication, there must be strict 10 safeguards in place that minimize the risk of 11 infection. These include using the medication for a 12 limited number of patients and for a single day only, 13 cleansing the stopper thoroughly between uses with 14 isopropyl alcohol or another suitable antimicrobial. 15 Refrigeration of vial between cases if there is a time 16 gap between consecutive cases and discarding the vial 17 if any breach or sterility is suspected." 18 And then it goes on to say, of course, you 19 only, you know, use a needle, one needle per patient, 20 et cetera. 21 If that is the process by which Dr. 22 Bhambhani administers the drug and "reuses the 23 single-dose vial," she follows those precautions, 24 would you agree that according to this article, she's 25 complying with an accepted standard of practice?</p>
<p style="text-align: right;">Page 107</p> <p>1 A You said a lot of things there. 2 Q I did, didn't I? There's not always one 3 way to satisfy the standard of care, right? There's 4 sometimes more than one standard practice, right? 5 A As a general statement? 6 Q As general statement, right. 7 A There are different ways to do things. 8 Q And I want to just hand you what's been 9 previously marked as 1619-10. It's an article. At 10 the top, just for the record, that says it's titled 11 "The Price of Cost Savings," Ray M. Baker, in the 12 Clinical Journal of Pain, June of 2008. 13 And did you review in Dr. Bhambhani's 14 deposition her description of the process and how she 15 administers the injection and what precautions she 16 takes? 17 A Yes. 18 Q Okay. So if you look at the second page of 19 this article, page 382, if you look at the right 20 column, the second paragraph up from the bottom, it 21 starts off "If a practitioner chooses." 22 A Yes. 23 Q And actually if you look a few lines up 24 from that, it says, "Given the reduced reimbursements 25 for interventional pain procedures." Do you see?</p>	<p style="text-align: right;">Page 109</p> <p>1 MR. STEINER: Objection as to form. You 2 can answer. 3 A According to the CDC, in which I place more 4 credence than this opinion, a single vial, a 5 single-dose vial should not be reused. And I don't 6 know why this clinician opined as he did. But even in 7 2012, I would not say that this was a reasonable 8 opinion based on the history of multiple outbreaks 9 related with reusing of single-dose vials. 10 Q Do you know Dr. Baker? 11 A No. 12 Q Are you familiar with this journal? 13 A I've heard of it. 14 Q Do you have an opinion, one way or the 15 other, whether this journal is a reasonably reliable 16 journal? 17 MR. COREN: Objection as to form. 18 A I don't. 19 Q And so you would disregard the expressions 20 made here this literature? 21 A I do not think that the statement of given 22 the reduced reimbursements for interventional pain 23 procedures and the push for cost-efficient care, a 24 case can be made for safely reusing a single-dose 25 medication, and that this is something that could be</p>